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RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex Parte JULIAN L. HENLEY

Appeal 2008-003199
Application 09/725,142
Technology Center 3600

Oral Hearing Held: May 21, 2009

Before MURRIEL E. CRAWFORD, JOSEPH A. FISCHETTI, and BIBHU R. MOHANTY, Administrative Patent Judges.

ON BEHALF OF THE APPELLANT:

WILLIAM G. NIESSEN, ESQ.
LARRY S. NIXON, ESQ.
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The above-entitled matter came on for hearing on Thursday, May 21, 2009, commencing at 10:24 a.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, 9th Floor, Alexandria, Virginia, before Kevin Carr, Notary Public.

THE CLERK: Calendar No. 60, Mr. Nixon.

MR. NIXON: Good morning.

JUDGE CRAWFORD: Good morning.

JUDGE FISCHETTI: Good morning.

JUDGE CRAWFORD: Mr. Nixon, who else do we have here?

MR. NIXON: We have the inventor, Dr. Julian Henley, right here.

JUDGE CRAWFORD: Oh.

MR. NIXON: And this is one of my staff members, Greg Niessen, who's a registered patent agent, and he's been working on this application.

JUDGE CRAWFORD: Oh, wonderful.

Well, welcome, and begin when you're ready.

MR. NIXON: All right.

Well, as you know, the marketing of health services is a topic that's right at the top of the list today. You read about it in the Post and the Times and all these newspapers.

This guy is trying to do something about it, and he's been waging a fight to do something about it for many years, having frustrated himself with working with insurance companies and the like.

He's trying to set up a virtual environment, where the ultimate user, the patient, can negotiate directly with the provider of the service.

And it's not just an auction. You can't have just an auction. And he'll explain in a little more detail here in a minute why that is so. But it's not so simple as just saying, "Oh, well, there have been auctions of things on

E-Bay and there's auctions of services of other kinds, et cetera. Why don't we just auction medical services?"

Well, if it was that simple, it would have been done a long time ago. It's not that simple. And there are a lot of special things that you have to do in order to have a successful commercial website of this kind, that pulls the user, the patient, directly together with the doctor, and lets all the legal and ethical requirements to be met at the same time.

I wanted to, if I may, just hand up to you some printouts from a website, if I may.

JUDGE CRAWFORD: Sure. Are these part of the record?

MR. NIXON: No. Well, if you want to make it -- if I can make them part of the record, of course I would love to do it; but I don't think you're going to let me do that.

JUDGE CRAWFORD: They're not -- (laughing).

MR. NIXON: The purpose of this is just to demonstrate to you that Dr. Henley is trying the best he can to scrape by and get some test marketing out there.

Unfortunately, this website does not practice this invention, or the inventions that we are here to discuss today. In order to get the funding that he needs, in order to expand this system into something that does practice the inventions that we're here to talk about today, we need a patent.

We need something that the investors will respect and look at, so that he can get the money that he needs in order to make this available to the public. This right now is a little test thing up in Seattle.

And it does show, it demonstrates -- and I think Dr. Henley will tell you about this -- we already have a lot of inputs from the public. They love it, they want something like this.

Unfortunately, without these inventions, without the extra investment that we can get with the patent, it's unlikely that this is going to be expanded nationwide.

If I could, I would like to also hand up some notes in the nature of what I would have on the screen, if I was talking. If I can do that --

JUDGE CRAWFORD: Certainly.

MR. NIXON: So that you follow along with my outline here.

Did I give you the one that's got my initials on it? (laughing). Let me give you another one. Here we go.

I don't have much time and I want to let Dr. Henley talk to you directly, so I'm not going to go into all of these things in great amount of detail.

But I do want to make just general comments. The Examiner here I think has used the broadest reasonable claim interpretation excuse for overlooking a lot of what is actually in the claims.

And also, the MPEP, as I've cited here, as I'm sure you people all are well aware of, really requires the Examiner to look at the specification through the eyes of a person skilled in the art.

And the inherency doctrine, of course, is strictly applied. I think the Examiner in this case has somewhat without proper consideration used the word "inherency". The preambles should be given limitations patentable effect as well.

The Direnzo reference is the main reference that the Examiner relies upon. But here, the negotiation that takes place is not between the ultimate patient; and a doctor who is going to provide some service, like surgery, for example.

This is really just a gatekeeper physician, your personal physician, who wants to get some x-rays read. And there is a way of, in effect, auctioning that service.

But the Direnzo system itself provides the service. The Direnzo system does not set up a meeting between a physician who's going to do surgery, for example, and a patient who needs surgery. It really just arranges for the reading of an x-ray at a remote site, and maybe at an off time on the East Coast as opposed to the West Coast.

With respect to something that's going to be important here, the physician, who is going to diagnose the x-ray, is listed there with some biographical information. But there's no indication that it is checked.

It leaves the qualification decision to the gatekeeper physician, who is arranging for the reading of the x-ray.

And the teaching of this reference is really limited to the reading of x-ray images; well, MRI's, x-rays, images of various kinds. You can see that if you look at the title, the claims, and figures.

And the queue-bidding process is somewhat limited as well.

The secondary reference, because the Examiner admits that Direnzo is not sufficient by itself to teach any of the things that have been claimed -- which I'll get into in a moment -- the Newman reference is actually almost irrelevant.

It does have to do with credentialling of doctors, but it does not provide for any automatic credentialling. It's simply a database that populates a form that the physician can then present to the hospital, and the hospital then must do the regular credentialling that the hospital normally does.

Physicians apparently have to get re-accredited every two or three years or so with each hospital that they practice in. And maybe they have other things that they have to fill out these forms for.

So this is a form-filling out service, where the doctor provides all of the basic information. The basic information is put into a database and then they have some kind of an automated process for filling out a particular form for the Presbyterian Hospital, and another one for the Methodist Hospital, and another one for the Catholic Hospital, et cetera.

All it does is just fill out forms.

JUDGE MOHANTY: Okay, Mr. Nixon, I agree with you that that's the way that reference operates.

MR. NIXON: Right.

JUDGE MOHANTY: It kind of just fills out the forms.

I want to get I think -- we're talking about Claims 1, 30 and 35?

MR. NIXON: Well, actually on the next page, my remarks, Claims 1 through 17 and 30 through 35 all have to do with automatic authentication of the qualifications of the service provider.

JUDGE MOHANTY: If I can just have you explain your specification. I think it's on page 20? That's -- how we should do our claim construction -- how the authentication is done.

MR. NIXON: This is page 20 of the specification?

JUDGE MOHANTY: I believe that's -- what you referred to me -- page 20. It's that first full paragraph there, the last sentence?

MR. NIXON: "The providers qualifications for performing the stated medical services are authenticated by means of a search engine 71, having a direct link to a qualifier base 72, and/or hyperlinks to one or more other qualifier databases 72."

Yes.

JUDGE MOHANTY: Okay.

MR. NIXON: So this system, if this -- this is one of the things that has to be done if this is going to be successfully practiced on a commercial scale nationwide.

You cannot have self-authentication or qualification. You're going to have literally tens of thousands, maybe hundreds of thousands of providers, doctors, who are trying to register in this thing; and millions of patients who are trying to negotiate.

And you have to have some way to automatically verify that every one of these physicians who is trying to sign up and become a registered physician is qualified to do so.

And then those qualifications have to be double-checked all the time, just like the hospitals have to double-check every year or two the physicians' qualifications. So would the qualifications of the provider here have to be automatically established and maintained.

And so this is an important feature of many of our claims; and that's why I've devoted all of the second page here mostly to --

JUDGE MOHANTY: Claim construction would extend to include the authentication with a qualifier database and search engine?

MR. NIXON: Yes.

JUDGE MOHANTY: Okay.

MR. NIXON: Mm-hmm. Absolutely.

JUDGE FISCHETTI: In a situation like Direnzo, if the company is licensed to produce I believe it's what, x-rays?

JUDGE MOHANTY: Image analysis.

JUDGE FISCHETTI: Then aren't they by virtue of that license?

MR. NIXON: I don't believe you're licensed just to read the x-rays. But maybe you are. There are radiologists who specialize in that; but one of the Direnzo teachings is that unfortunately a lot of other doctors read x-rays apparently in their spare time as well.

And he does, of course, want to have qualified people reading the x-rays. I don't recall him talking about companies being qualified and licensed; but the individual diagnostic physician, who's going to read the x-ray, would have to have some kind of qualifications, supposedly.

And he does provide biographical information, so that the gatekeeper physician can read the biographical information that has been self-posted by the person who's offering to read the x-ray.

JUDGE FISCHETTI: I guess my question is: So I go to a service provider, such as Direnzo. Do I automatically get an authenticated professional when I walk in the door?

MR. NIXON: My answer is "No". And the Examiner has agreed with that. That's one of the deficiencies. That's why he cited Newman. You don't because it's only a self-submitted biographical information that has to be sifted in an analog way, if you will, by the gatekeeper physician.

The gatekeeper physician, before he engages in services of the provider, can, of course, access the biographical information, and read it, for what it's worth.

It may be all fake.

So the gatekeeper physician, if he's going to do his due diligence, unless he knows this individual, he might have to go do his own verification checking before he actually entrusts this guy. Or maybe he's used him before and he knows him, and he's willing to do that.

But there is no automatic verification. There is simply a cataloguing of self-provided biographical information, is the way I read Direnzo in a way the Examiner read Direnzo. And that's why he cited Newman as a secondary reference.

JUDGE MOHANTY: So there's essentially no enforcement, that someone logging onto the system could --

MR. NIXON: That's right. There's no independent -- it's just by --

JUDGE MOHANTY: It's just my word, then?

MR. NIXON: It's just by --

JUDGE MOHANTY: Okay.

MR. NIXON: You have to take the word of whoever it is that's signing up to provide the services, that they know what they're doing.

I could borrow the credentials of Dr. Henley, for example, and sign myself up, I suppose, and pretend to read these images. And until I got caught some way or another, there would be no way for the system to catch me. It would have to be somebody who was using my services, noting that I'm incompetent. Or the like.

So this is a very important aspect of many of our claims. It's not the only aspect.

Now unfortunately, in this case, as Dr. Henley may tell you, he wishes he had all of his claims in one basket here. We had a restriction requirement earlier on that forced us to splinter out a lot of things.

So what we're talking about here are a number of claims which have a number of different features. Each of those features has some important component to play in the overall system that we hope to put out nationwide, if we can get financing. And getting financing, of course, is one of the reasons we're here.

JUDGE MOHANTY: I think we understand your position on Claims 1, 30, and 35.

If we can move on to Claim 21, this doesn't include that limitation.

MR. NIXON: That's right. The claim -- on page 3, in fact, of my remarks. Claims 12 and 21 do have, however, a different thing. There, when the patient bids, the prospective provider is automatically provided on line with both help and financial information about the bidder, so as to help the provider to determine what kind of response to make.

And here, the Examiner says, well, the medical image that's being supplied in Direnzo is medical information. That's not the kind of medical information, of course, we're talking about here.

We're talking here about if the patient is asking for a surgery, for example, have they previously had similar surgery? Have they had

complications? Do they have diabetes? Are they overweight? Those kinds of things which would affect the way in which the provider bids on the thing.

And of course, the financial information: Do you have insurance and do you have other means to pay, et cetera, would also bear on the decision.

JUDGE MOHANTY: Well, your claim just recites to obtain information described in --

MR. NIXON: Well, I don't think so. Because the reason the x-ray is there is it doesn't self-describe the health. The x-ray is actually being presented to the diagnostic physician in order to get some information about the health.

JUDGE MOHANTY: Okay.

MR. NIXON: And it's only a small piece, and it has nothing to do with the service. In other words, the service that is being provided here is not graded upon the difficulty of reading the x-ray.

Which might be, in other words, if you had an x-ray which of somebody that has a pacemaker and a lung transplant, and a lot of other miscellaneous stuff in there, that might be relevant information that the provider would like to know, but it's not provided for them.

JUDGE MOHANTY: I'm not totally convinced about that argument. But I'd like to move onto the second argument about Claim 21.

MR. NIXON: Right --

JUDGE MOHANTY: Which dealt with forwarding the online bid -- forwarding the received online bid with that information to the health care provider?

MR. NIXON: Right.

JUDGE MOHANTY: Okay. So is your position that in the prior art, like the bid is there someplace, with the x-ray? And then the physician has to go look at. But you're saying that this is automatically forwarded to --

MR. NIXON: That's correct --

JUDGE MOHANTY: The physician.

MR. NIXON: That's another difference.

JUDGE MOHANTY: Okay. And so that's not shown in the prior art?

MR. NIXON: That's correct.

DR. HENLEY: The same condition.

JUDGE MOHANTY: Okay.

MR. NIXON: Right. The things that might cause the provider to say, "No, I don't want to bid on this," or "If I bid on this I'm going to have more money because this is a complicated situation."

JUDGE MOHANTY: And that's the automatic forwarding that --

MR. NIXON: Yes. Right. That's an important part of it.

JUDGE MOHANTY: Okay. I

MR. NIXON: The next item is Claims 50 through 53. And there the Examiner doesn't seem to understand, we're providing information from one provider to another provider about past patient compliance.

This is not something where the buyer of a service is saying, "Oh, you know, Dr. Joe is a good guy," et cetera. No, this is where Dr. Joe is talking to Dr. X and explaining that this particular patient has a bad history or this particular patient has a good history, or this particular patient has a complicated history of some kind, which you need to take into account when you're making this bid.

Again, these are aspects that are extra to just a straightforward auctioning of medical services.

JUDGE FISCHETTI: Can I interject one question here?

MR. NIXON: Sure.

JUDGE FISCHETTI: How would that square against privacy issues, which would basically come under a usefulness requirement of this claim?

MR. NIXON: There could be issues there that will have to be addressed separately by maybe patient permission, for example.

And that's not addressed in our claim.

JUDGE FISCHETTI: Okay.

MR. NIXON: But in order to actually implement that -- and Dr. Henley will tell you about some more things too, that in the real world there are additional things, in addition to what we're talking about here, of course.

JUDGE MOHANTY: Mr. Nixon, I just want to ask you, in Claims 50, 52, and 54, you talk about the doctor leaving feedback --

MR. NIXON: Right --

JUDGE MOHANTY: Specifically about whether the patient follows instructions and the resultant outcome of the surgery.

MR. NIXON: Right.

JUDGE MOHANTY: Now I'll agree the prior art doesn't specifically show feedback on those two parameters.

MR. NIXON: Right.

JUDGE MOHANTY: But the prior art does talk generically about feedback.

MR. NIXON: Yes.

JUDGE MOHANTY: So I just want to know why it wouldn't be obvious. I mean, you leave feedback, does he pay on time? You know, that kind of thing. Why wouldn't it be obvious --

MR. NIXON: Well, this is feedback from one provider to another, rather than from the buyers to another. In other words --

JUDGE MOHANTY: Okay. Is it on the claim where -- because --

MR. NIXON: Yes.

JUDGE MOHANTY: Because I just think it's collecting the feedback information.

MR. NIXON: No, Claim 50, for example, let me get the claims out here. Where have I got the claims?

DR. HENLEY: Can I say something?

MR. NIXON: Yes. Sure. Maybe you know the answer.

DR. HENLEY: While you're looking up?

There are feedbacks we divided into transactional feedback. It means how was the interaction? And that's a much more important factor is what we call the medical complexity feedback.

It a patient comes in for gallbladder, and they're seen, it can be done on an outpatient basis. If they weigh 400 pounds and they have diabetes, that has to be done in a hospital, under different --

So we need to know that there's a medical complexity rating. So without interposing HIPAA regulations, each patient has what we call a medical complexity rating, whether there's an another medical condition associated.

And those are the critical parts that make a health auction possible.

MR. NIXON: And it's Claim 51 that actually does require that. Let me see -- hopefully Claim 52 does as well.

JUDGE MOHANTY: I didn't see any independent claims. I'm not sure if -- Claim 51 specifically.

MR. NIXON: Well, Claims 51 and 53, the dependent claims, are the ones that actually require the service provider to be provided with the feedback information from another service provider.

JUDGE MOHANTY: Okay.

MR. NIXON: And I apologize. Quickly looking at this, 50 and 52 I don't think do have that requirement. Sorry.

JUDGE MOHANTY: Okay. So I just want to hear your argument that if we know that feedback was used in the art, do you have any arguments why it wouldn't be obvious to specifically leave feedback for failed instructions or the resultant outcome -- or following instructions.

MR. NIXON: Yes. Because it's feedback of a different kind and subject to different moral and ethical requirements has been indicated here.

It's not obvious that you can provide feedback from one provider to another provider, for example.

JUDGE MOHANTY: And like I said, that's not in those independent --

MR. NIXON: It's in the dependent claims, you're right. It's not in the independent claims.

JUDGE MOHANTY: Okay. And then in I think 56, there's nothing about the specific feedback for followed instructions with the resultant outcome. It's just leaving feedback.

MR. NIXON: Yes, 54 through 57 --

JUDGE MOHANTY: Well, in 54 you're talking about the resultant outcome; 56 is a claim where it just talks about feedback. And like I know on E-Bay --

MR. NIXON: Right --

JUDGE MOHANTY: That's not of record here in this case, but I know that both buyers and sellers do leave feedback --

MR. NIXON: Yes. And the Examiner has cited some art that shows feedback generically in that context.

JUDGE MOHANTY: Yes.

MR. NIXON: So there are some claims that are not as strong as others.

JUDGE MOHANTY: Okay.

MR. NIXON: (Laughing). But Dr. Henley hopefully will have time here, if I can --

JUDGE MOHANTY: Okay. And before you step up, I just want to ask you about Claim 58, that's also the CPT codes.

MR. NIXON: Sure. And that's the next page four, 58 through 60, I think are pre-arranged price adjustment after the bid acceptance if unexpected circumstances arises. And Dr. Henley can fill in more about this.

But in this particular field, you may actually accept a bid for a tonsillectomy and find out that it has to have the larynx removed, or something.

And so there's a way in which you can equitably prevent bait-and-switch. For example, he wants to make sure that he doesn't permit doctors to bait and switch, to agree to perform something and then later find out that, well, you have to do something a little bit different.

And therefore, there is a system built into here, using these CPT codes relative value scale, so that you can -- okay, you need some little different service; but there is a way in which we can calculate how much more or how much less that different service might be, so that you still have an enforceable contract, if you will, where the doctor can't get out of it.

He's bid to do it at a certain price. It may be adjusted up or down, but it's adjusted up or down in accordance with a CPT code relative value scale.

JUDGE FISCHETTI: Is that practiced in the insurance industry today?

MR. NIXON: I don't know. Doctor, do you know?

DR. HENLEY: CPT 4 and medicare bases its reimbursement on a relative value scale.

JUDGE FISCHETTI: All right.

DR. HENLEY: They're payments. What we're using in here, is to stabilize the pricing and lock the doctor or the provider, so he doesn't offer some low-ball price on one procedure and then switch it into an upper price.

So he is locked into the currently practiced relative value scale, which medicare works on.

MR. NIXON: And Claim 5, we have that the time and location and automatically computed price is a function of the base price, using a fraction of the difference quantity, et cetera. Frankly, Kenna is irrelevant about this.

But that's only one claim in Claim 5.

JUDGE CRAWFORD: You're running a little bit --

MR. NIXON: Yeah. And I'm going to right quickly here.

The terms of payment in advance, okay. And the CPT ICD9 coding is support for proffered medical services, this is different than using it after you've had the medical service to pay for the medical service, which is commonly done.

But here, in proffering the medical service, you use that code, so that you can tie the doctor down to "Yes, this is specifically what I'm talking about; not some little nuance of different words that are being used, and then a game can be played: "Oh, well, you know, what I really meant was such and so."

So let me shut up now and let Dr. Henley talk for a just a minute or two, please.

JUDGE CRAWFORD: Just a minute, yes.

DR. HENLEY: All right. Thank you for giving me the opportunity to speak on behalf of this technology.

I'll speak a little bit more in general terms from the inventor's standpoint, as some of the legal aspects escape me.

Just to give you a little background, I am not new to patents. I have about 30 patents in the device area and biotechnology. I did the artificial voice box and other medical patents.

I find that this one is really the most challenging, and also the most beneficial. I believe that I can save more lives with this technology than I can in the operating room.

Because I have seen too often people being marginalized from access to health care, because of profit margins that the gatekeepers exercise.

So I want to read you a statement of the problem, and this is really from the Department of Health and Human Services Policy Analysis, Mr. Moffit:

"The problem, then, is not that the market has failed in health care. Rather the problem is that the market has not been tried, at least not in more than 30 years.

"For a market to be tried requires active powerful participation by the market's two key decision-makers: The provider and the consumer.

"And as long as the consumers are shielded from the true costs of their health care, providers will continue to offer a growing volume of services at whatever prices they can obtain.

"In the end, health care costs will continue to escalate. If Congress is to solve the problem of escalating health care costs, it must do so either by rationing and regulating the consumer's access to medical service, or by introducing genuine free-market reforms."

Now the sad part to this part, this was identified and stated and advised to the Congress 20 years ago by Mr. Moffit.

We in the private sector, have made an effort to bring those market forces to bear on health care, and created an online auction. It's unlike anything that's been done before, because if an auction was obvious, it would have been done before.

We operate in health code constraints, in addition to physical laws. In the previous inventions, I only had to deal with science. This one I have to deal both with the science, the electronics, as well as the existing health code.

So, for example, with something simple, do you know that it's not legal for a physician to sell or discount a health service? So in a way, we create -- and in this patent it got split, but we literally create a health care option, where a patient locks the physician into a specific price for a specific service.

To protect the patient, we also stabilize it with CPT codes, which are clear descriptions. Right now CPT codes are used to protect the insurance companies. I want to use the codes to protect the patient.

The Direnzo patent is a way for radiologists to go to the Caribbean and online to reading of x-rays to supplemental their little vacation. It's a way to generate a higher price for the doctor.

I'm creating a system that generates a lower price for the consumer, because it pits one physician against the other to compete for the patient, based on their quality, their price.

We're offering qualification transparency, pricing transparency, and outcomes transparency, if we're allowed to thrive.

Now this system -- you know, obviously by the time the patent attorneys got to it, I don't even understand my own invention. Because it got split into -- first we put it all into 52 claims, then the claims got split into

six other entities. And now I'm told that the stuff in the first set of claims that's related in the third set of claims don't stand independently.

But that's my limitation; I'm the science guy who's trying to make this happen. We are now in a commercial phase. I have founders. We raised some private money. We went on line in Seattle. We've gotten tremendous response from the consumer market.

I need the patent issue for the confidence of raising additional money to go into northern California. Investors are saying, "Well, we've never seen anything like this. It's new. Is there a patent thing?"

I say yes, we've been pending for many years.

So to conclude my little shtick, let me read you a comment from one of the consumers. This is not my words, this is from a fellow called C. B. Princeton:

"I'm a big fan of Price Doc and its unique approach. It is addressing a market need as more and more people seek alternatives to the rising cost of health care. It's about time the private sector stepped up to help make medical procedures more affordable.

"These guys have a brilliant concept and if they launch it in Seattle, it should be a no-brainer to take it into larger markets such as California.

"Despite all the support health care reform may get from Washington, it will not be enough. So we will need private sector initiatives to help shoulder the burden.

"We must support programs like Price Doc and innovate our way out of a very large and complicated health care system, that is not affordable to the very large percentage of the population.

"Well done, Price Doc."

JUDGE CRAWFORD: Thank you.

DR. HENLEY: Thank you.

JUDGE CRAWFORD: Do you have any questions?

JUDGE FISCHETTI: No, I don't.

JUDGE CRAWFORD: Any questions?

JUDGE MOHANTY: No.

JUDGE CRAWFORD: Thank you.

MR. NIXON: Thank you very much for letting us run over a bit.

(Whereupon, at 10:56 a.m., the proceedings were concluded.)